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No. 98-235

FILED
NOV 13 1998
OFFICE OF THE CLERK
SUPREME COURT, U.S.

In The

Supreme Court of the United States

October Term, 1998

NUTRITIONAL HEALTH ALLIANCE and SOO MAN SHIM, d/b/a NEW NUTRISSERIE,

Petitioners,

vs.

DONNA SHALALA, in her official capacity as Secretary, U.S. Department of Health and Human Services, and DAVID KESSLER, Commissioner, Food and Drug Administration,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Second Circuit

REPLY BRIEF FOR PETITIONERS

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Petitioners Nutritional Health Alliance and Soo Man Shim, d/b/a New Nutrisserie, respectfully submit this reply brief in support of the Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit.

ARGUMENT

1. Respondent contends that Petitioners lack Article III standing to challenge the prior authorization requirement of the NLEA/FDA regulatory scheme. However, both the District Court and the Court of Appeals correctly found that Petitioners do have standing in this case with regard to the prior restraint issue. The Court of Appeals explained:

> It involves a purely legal question that is eminently fit for judicial review. Plaintiffs will necessarily be subjected to the prior restraint as a result of our conclusion that we will not consider their underlying argument until they submit an actual health claim for FDA approval. This follows from the fact that even those claims that will eventually be authorized by the FDA — and that are presumably truthful — are nevertheless subject to the allegedly unconstitutional FDA preclearance procedure. We therefore can consider this second challenge on the merits.[14]
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> * * * *
>
> [14] There is also no doubt that plaintiffs have standing to raise the prior restraint claim. The delay that they will face as soon as they submit a proposed health claim to the FDA constitutes a concrete injury in fact. For during the 540-day FDA review period the manufacturers and retailers will be prohibited from giving, and the consumers prevented from receiving, information allegedly protected by the First Amendment.

(Pet. App. 14a).

Further, the District Court found that plaintiffs have set forth examples (*e.g.*, with regard to Vitamin E) of non-misleading emerging health information which are presently blocked by the prior restraint at issue in this case. (Pet. App. 33a n.13). FDA has already announced that with regard to emerging health claims, the agency will never approve them — no matter how truthful and non-misleading such claims may be. (*See* Pet. 22-24). Accordingly, there is no doubt that Petitioners do have standing to raise the prior restraint issue.

2. Respondent ignores the fact that the first question presented for review by the Petition relates to a longstanding issue left unresolved by this Court in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), *i.e.*, whether and to what extent the traditional prior restraint doctrine applies to commercial speech. *Id.* 447 U.S. at 571 n.13.

In opposing Petitioners' request for certiorari in this case, Respondent contends that "the prior restraint doctrine does not appear to play any distinct role in commercial speech cases." (Opp. Br. 8). However, Respondent's position is contrary to the decision of the Court of Appeals in this case[1] which clearly held that "the prior restraint doctrine does play a role in evaluating the regulation of commercial speech" (Pet. App. 15a) — albeit in only a limited way.

The Court of Appeals held that a prior restraint of commercial speech is subject only to a modified *Central Hudson* test.[2] (Pet.

1. In light of Respondent's disagreement with the standard adopted by the Court of Appeals, it is surprising that Respondent opposes a grant of certiorari to resolve the issue.

2. As noted in the Petition, while the Court of Appeals did recognize that the prior restraint doctrine does apply to commercial speech, the Court limited its analysis in this case to determining only whether the prior restraint at issue satisfied the fourth prong of the familiar four-part *Central Hudson*

(Cont'd)

14-21). In doing so, the Court of Appeals failed to apply the full *Central Hudson* analysis *to the prior restraint at issue* and, consequently, it completely avoided making the specific determinations that *Central Hudson* requires if it is to be applied to prior restraints of commercial speech. *See Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) and *44 Liquormart Inc. v. Rhode Island*, 517 U.S. 484 (1996). The issue posed by the present petition is whether the Court of Appeals was correct in adopting a standard which bypasses the full *Central Hudson* test as regards a prior restraint of commercial speech.

Respondent has refused to address the urgent reason why certiorari should be granted in this case: the fact that there are conflicting views among the circuits, in the lower courts, and on the part of the Government, as to the standard to be applied to the permissibility of prior restraints of commercial speech. (*See* Pet. 15-16)[3].

(Cont'd)

test (*i.e.*, whether the restraint is "not more extensive than necessary") (Pet. 18-20) which the Court of Appeals then treated as a "reasonableness" test, contrary to the interpretation of the fourth prong as defined in other decisions of this Court. (*See* Pet. 14-21).

3. Respondent concedes that the Court of Appeals did not apply the *Central Hudson* four-pronged test as part of its prior restraint analysis. (Opp. Br. 10). However, Respondent contends that:

> The Court of Appeals did not engage in that analysis . . . because it had already concluded that petitioner's challenge to the "significant scientific agreement" standard is not ripe for review . . . Having concluded that petitioner's challenge to that standard is not ripe, *the Court of Appeals correctly declined to assess the merits of that standard as part of its inquiry into whether the preauthorization review constitutes an unconstitutional prior restraint.*

(Opp. Br. 10-11) (emphasis added).

(Cont'd)

The Second Circuit holds that the prior restraint doctrine does apply to commercial speech in a limited way. (Pet. App. 15a). The Sixth Circuit has held that it does not. *Record Revolution No. Six v. City of Parma*, 638 F.2d 916, 936 (6th Cir. 1980), *vacated and remanded for reconsideration*, 456 U.S. 968 (1982). And the Eleventh Circuit has stated that the "scope and breadth of the principle against prior restraint in the realm of commercial speech has yet to be charted." *Kleiner v. First National Bank of Atlanta*, 751 F.2d 1193, 1207 (11th Cir. 1985). The issue here relates to the permissibility of prior restraints on protected commercial speech, and most recently, four judges of the Ninth Circuit, dissenting from a ruling denying a rehearing *en banc*, have stated that:

(Cont'd)

Respondent's contention is nothing short of a sleight-of- hand attempt on its part to dodge the true question raised by the Petition. Petitioners *do not claim* that the Court of Appeals failed to apply *Central Hudson* to the "significant scientific agreement" standard "*as part of its inquiry* into whether the preauthorization review constitutes an unconstitutional prior restraint." Petitioners contend that the Court of Appeals failed to follow the dictates of *Central Hudson* in evaluating the imposition of the prior restraint itself. As noted in the Petition: (1) the Court of Appeals did not determine under *Central Hudson's* second prong whether the Government has any interest in requiring the content of commercial speech to be *anything other than truthful and non-misleading before it can be communicated* — whatever the standard (Pet. 19); (2) the Court of Appeals did not hold the Government to its burden under the third prong to demonstrate that the prior restraint directly and materially advances the Government's interest (Pet. 19-20); and (3) the Court of Appeals approved, purportedly under the fourth prong, the 540-day prior restraint before judicial review as "reasonable" despite the availability of other less restrictive regulatory alternatives. (Pet. 20-21). The reviewability of these issues are not dependent in any way on the reviewability of the wholly separate questions raised by the Petition of whether the Court of Appeals erred by declining to review the "significant scientific agreement" standard (Pet. 22-26) *or* whether that standard itself fails the *Central Hudson* test. (Pet. 26-28).

> Only unprotected "commercial speech" — *i.e.*, "[f]alse, deceptive, or misleading, *advertising*," *In re R.M.J.*, 455 U.S. 191, 200 [parallel citations omitted] (1982) (emphasis added) — has ever been subjected to prior restraint.

San Antonio Community Hospital v. Southern California District Council of Carpenters, 137 F.3d 1090, 1092 (9th Cir. 1998). *See also Lowe v. Securities & Exchange Commission*, 472 U.S. 181 at 235 (1985) (concurring opinion).[4]

In this case, the Court of Appeals authorized a 540-day prior restraint which Petitioners believe violates virtually any standard that ultimately will emerge in this critical area of the law. The crux of the problem, however, is that this Court has not yet identified the standard that should be applied and, therefore, certiorari is fully warranted to deal with this issue of major public importance to all businesses, industries, and individuals who exercise their First Amendment commercial speech rights.

Accordingly, the differing views expressed on this important Constitutional issue by this Court, the Courts of Appeal, the District Courts, and the Government demonstrate conclusively that the

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4. In *Lowe*, Justice White, then Chief Justice Burger, and Chief Justice Rehnquist raised the question of whether the Government-sought prior restraint should have been held to violate the First Amendment:

> Based on petitioner's past misconduct, the Government fears that he may in the future publish advice that is fraudulent or misleading; and it therefore seeks to prevent him from publishing *any* advice, regardless of whether it is actually objectionable. Our commercial speech cases have consistently rejected the proposition that such drastic prohibitions on speech may be justified by a mere possibility that the prohibited speech will be fraudulent.

Id. (emphasis in original).

question of the applicability of the First Amendment prior restraint doctrine to commercial speech is one that cries out for resolution by this Court. In this light, Respondent's opposition to certiorari on this issue is inexplicable. It is hard to imagine a more compelling case for this Court's intervention than to establish the definitive standard that the Government and the Courts should apply in determining in the first instance whether a prior restraint on content-based commercial speech should be imposed.

3. In support of Respondent's further argument that Petitioners lack standing to seek review separately of the merits of the "significant scientific agreement" standard itself, Respondent repeatedly states that Petitioners have not alleged that they want to make any particular health claim nor that FDA has denied them permission to make any particular claim. (Opp. Br. 8, 11, 13).

Respondent's argument is entirely without merit. The District Court in this case expressly found that "at least some health claims can be presented in a non-misleading fashion" (Pet. App. 33a) and cited the following as one example:

> A study published in the American Medical Journal reports that Vitamin E supplements may reduce the progression of coronary artery disease. This is not an established fact and is still being studied.

Moreover, as noted in the Petition, the FDA has in fact already ruled, after a full administrative proceeding, that it will not approve any health claim based on preliminary or developing scientific information, opinion, or studies (which by definition FDA cannot ever find to be supported by "significant scientific agreement") — no matter how truthful and non-misleading such claims may be. (*See* Pet. 22-24). This position caused the tragic and unwarranted delay in FDA approval of the health claim relating the consumption of folic acid to the prevention of birth defects (*See* Pet. 4 n.4) and is the basis for FDA's more recent refusal to

approve health claims relating the consumption of Vitamin E to the prevention of heart attacks (even though FDA admits that it may be banning claims "in the interim" that might "ultimately be shown to be scientifically valid, truthful, and not misleading"). (*See* Pet. 19 n.35).

Thus, contrary to Respondent's contention, the record more than sufficiently provides the evidence necessary to determine whether the "significant scientific agreement" requirement actually and unconstitutionally bars any truthful and non-misleading speech.

CONCLUSION

For the reasons stated herein, and for the reasons stated in the Petition, it is respectfully requested that a Writ of Certiorari issue to review the judgment of the United States Court of Appeals.

Respectfully submitted,

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